

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Pulmonary Allergy Drugs Advisory Committee (PADAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

January 29, 2013

QUESTIONS

1. **DISCUSSION:** Discuss the bronchodilator efficacy data for olodaterol.
2. **DISCUSSION:** Discuss the overall safety profile of olodaterol.
3. **DISCUSSION:** Discuss the proposed exercise claims for olodaterol, including the following:
 - a) design of trials (e.g. duration, timing of medication and exercise testing)
 - b) minimum clinically important difference for exercise endurance, and
 - c) increased inspiratory capacity (IC) during exercise
4. **VOTE:** Considering the totality of the data, has olodaterol demonstrated substantial evidence of efficacy for the long term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema?
 - a) If not, what further data should be obtained?
5. **VOTE:** Is the safety profile of olodaterol adequate for approval for the long term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema?
 - a) If not, what further data should be obtained?
6. **VOTE:** Based on the information included in the briefing materials and presentations, has the applicant provided sufficient efficacy and safety data to support marketing of olodaterol inhalation solution for the long term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema?
 - a) If not, what further data should be obtained?